

PCT

To:

see form PCT/ISA/220

E I N G A N G
R E C E I V E D

0 7. Dez. 2004

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/051841

International filing date (day/month/year)
19.08.2004

Priority date (day/month/year)
21.08.2003

International Patent Classification (IPC) or both national classification and IPC
A61K31/44, A61J3/00

Applicant
ALTANA PHARMA AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

10/568417
International application No.
PCT/EP2004/051841

IAP20 Rec'd 14 FEB 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	9-12, 18
	No: Claims	1-8, 13, 14, 15, 16, 17, 19, 20
Inventive step (IS)	Yes: Claims	
	No: Claims	1-20
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/051841

AP20 Rec'd PCT/PTO 14 FEB 2006

Re Item V.

- 1 The following documents are referred to in this communication:
D1 : "Section 3 - Summary of Product Characteristics" PROTIUM -PRODUCT SUMMARY. ISSUED BY BYK GOLDEN , DE, January 2000 (2000-01), XP002163617
D2 : US 2003/003058 A1 (LINDER RUDOLF ET AL) 2 January 2003 (2003-01-02)
D3 : LEITNER ET AL: "Visuelle dokumentation der Stabilität der intravenösen Lösungen von Omeprazol und Pantaprazol" WIEN.MED.WSCHR, vol. 152, 2002, pages 568-573, XP001204762
- 2). D1 discloses that the marketed product "Protium" is in freeze dried form in a glass vial with an aluminum cap and rubber stopper. Zinc is not present. This disclosure falls within the scope of claims 1, 2, 3, 5, 7,8, 13, 17, 19, and 20 under Article 33(2) PCT.
- 3). Both D2 and D3 disclose proton pumps in solution for injection. No zinc is disclosed. These documents therefore fall within the scope of claims 1-8, 13, 14, 15, 17, 19 and 20 under Article 33(2) PCT.
- 4). The subject-matter of the remaining claims would appear to rely on the use of known techniques. These claims therefore cannot be regarded as inventive under Article 33(3) PCT.